JUL 1 3 2000

K000647

Premarket Notification 510(k) Summary
As required by section 807.92
DATEX-OHMEDA NETWORK AND CENTRAL

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

February 25, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

DATEX-OHMEDA NETWORK AND CENTRAL

COMMON NAME:

Clinical Network and Central Station

CLASSIFICATION NAME:

System, network and communication, physiological monitors (per 21CFR 870.2910)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

DATEX-OHMEDA NETWORK AND CENTRAL is substantially equivalent to the legally marketed (predicate) DATEX-ENGSTROM NETWORK (K974101).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda Network and Central is a system which consists of networked devices and the actual networking hardware. The networked devices are Datex-Ohmeda products containing a network adapter for physical access to the Datex-Ohmeda Network as well as software modules supporting network access. Examples of currently available networked devices are:

1. Datex-Ohmeda AS/3 Anesthesia Monitor
2. Datex-Ohmeda AS/3 Network Link
3. Datex-Ohmeda AS/3 Compact Monitor
4. Datex-Ohmeda CS/3 Critical Care Monitor

Datex-Ohmeda, Inc.
Three Highwood Drive
Tewksbury, MA 01876
www.datex-ohmeda.com

Telephone: 800-635-6099
978-640-0460
Facsimile: 978-640-0469

5. Datex-Ohmeda CS/3 Compact Monitor

6. Datex-Ohmeda Light Monitor

7. Datex-Ohmeda Cardiocap 5 Monitor

8. Datex-Ohmeda Network and Central, included in this 510(k)

The Datex-Ohmeda AS/3 Record Keeper is also related to the Datex-Ohmeda Network as an application using the services provided by the Datex-Ohmeda Network.

The Datex-Ohmeda Central is the primary maintainer of communication between other networked devices and is, thus, an essential part of the network. The structure and functionality of the network closely corresponds to the structure and functionality of the substantially equivalent device Datex-Engstrom Network and Information Center (510(k) number: K974101).

The Datex-Ohmeda Network will be used for real-time communication between devices, for record keeping and for data management in a hospital. Practical examples of currently available features are:

- Transmission and display of measured values and alarms in the Datex-Ohmeda Central screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication).
- Anesthesia record keeping.
- Storing and transferring of trend and record keeping data in the network. When the patient is moved from one monitor to another, the data can be transferred with the patient. This feature includes also transferring data from/to an external system (HIS, laboratory, etc.) to/from Datex-Ohmeda Network.
    - Printing of anesthesia records, ICU reports, trend print-outs, spirometry loop print-outs, waveform snapshot print-outs, etc.

The actual networking hardware consists of cabling, patch panels, racks, connectors, repeaters, etc. The networking hardware is similar to the networking hardware of the substantially equivalent device Datex-Engstrom Network (510(k) number: K974101).

The Datex-Ohmeda ViewStation is a Datex-Ohmeda Central version that can show real-time curves and numeric information from any monitor residing in the Datex-Ohmeda Network. It also allows printing to laser printer or recording to a strip-chart recorder. The Datex-Ohmeda ViewStation does not store patient data, or provide any other network services than display and printing services. The ViewStation uses the same hardware and a subset of the software used by the main Central.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda Network and Central is intended to be used with Datex-Ohmeda devices for displaying, storing, printing and otherwise processing information received from other networked devices.

The Datex-Ohmeda Network transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several Centrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda Central maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).

The Datex-Ohmeda Central can be used for storing, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda ViewStation can be used for printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Network and Central is substantially equivalent in safety and effectiveness to the Datex-Engstrom Network and Information Center (510(k) number: K974101) currently in distribution.

The structure and functionality of the Datex-Ohmeda Network and Central closely corresponds to the structure and functionality of the Datex-Engstrom Network and Information Center (predicate): The basic architecture of Datex- Ohmeda Network and Central is similar to that of Datex-Engstrom Network and Information Center (predicate).

The implemented changes have been technological enhancements made to improve the usability and performance of the system, as well as to make more patient data available for the users of the Datex-Ohmeda Information Center. The Datex-Ohmeda Network, including Datex-Ohmeda Central, is as safe and as effective as the current Datex-Engstrom Network (predicate) version.

The main reason for the submission of this 510(k) application is the change in the software platform: Datex-Ohmeda Information Center used runs on top of a DOS operating system, and the new version runs on Windows NT 4. Additionally, the size of the Datex-Ohmeda Network has been increased by allowing separate Datex-Ohmeda Monitor Networks to communicate with each other via a TCP/IP backbone network. These changes have been made possible by the increased computing power of modern personal computers that the Datex-Ohmeda Central and ViewStation softwares run on.

New features in the Datex-Ohmeda Central are the implementation of the second selectable waveform and numeric field in the multiview and an optional strip-chart recorder. The strip-chart recorder can function both in a continuous mode triggered by alarms, or in a manual mode.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The DATEX-OHMEDA NETWORK AND CENTRAL is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following voluntary standards have been made:

EN60950: 1995 (IEC950 2nd edition)
EN 55022: 1994 (IEC-CISPR 22)
EN 55082-1: 1991 (IEC 801-2, IEC 801-3, IEC 801-4)
EMC Directive 89/336/EEC (including amendments)
Low Voltage Directive 73/23/EEC (amended by 93/68/EEC)
IEC 60601-1-2, Radiated Emission (IEC-CISPR11)
IEC 60601-1-2, Immunity to Electrostatic Discharges (IEC-61000-4-2)
IEC 60601-1-4 Medical electrical equipment. Part 1: General requirements for safety
4. Collateral Standard: Safety requirements for programmable medical systems.
CAN/CSA-C22.2 No 950
UL1950
ISO/IEC 8802-3 (ANSI/IEEE 802.3), EIA/TIA-568, EIA/TIA-TSB40

Conclusion:
The summary above shows that there are no questions of safety and effectiveness for the DATEX-OHMEDA NETWORK AND CENTRAL as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2000

Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Re: K000647
Datex-Ohmeda Network and Central
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: June 15, 2000
Received: June 16, 2000

Dear Mr. Kent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K000647

Device Name: Datex-Ohmeda Network and Central

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000647

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)